

Notice of Allowability

Application No.

10/803,541

Applicant(s)

BRODSKY, GARY

Examiner

Anand U. Desai, Ph.D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 30, 2007.
2. ☒ The allowed claim(s) is/are 1, 4, 6-8, 14, 23, 47, 48, 50-52, and 60-62.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2007 has been entered.
2. Claims 1-8, 14, 23, 42-48, 50-52, 58, and 60-62 are currently pending. Claims 23, 42-45, 61, and 62 are withdrawn. Claims 1-8, 14, 46-48, 50-52, 58, and 60 are currently under examination.

Election/Restrictions

3. Claims 1, 4, 6-8, 14, 47, 48, 50-52, and 60, drawn to products are allowable. The restriction requirement between groups I, IV, and VIII, as set forth in the Office action mailed on June 29, 2005, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claim 23, 61, and 62, directed to methods are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may

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be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Withdrawal of Rejections

4. The rejection of claims 1-8, 14, 46, and 58 under 35 U.S.C. § 112, second paragraph is withdrawn.
5. The rejection of claims 1-8, 14, 46-48, 50-52, 58, and 60 under 35 U.S.C. § 112, first paragraph, scope of enablement is withdrawn.
6. The rejection of claims 1-5, 7, 8, 14, 46-48, 50, 51, 58, and 60 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is withdrawn.
7. The rejection of claims 1-8, 46, and 58 under 35 U.S.C. 102(b) as being anticipated by Kilic, F. et al. (Journal of Biological Chemistry, 272(8): 5298-5304 (1997); Cited in 10/19/2005 office action) is withdrawn.
8. The rejection of claims 14, and 60 under 35 U.S.C. 102(e) as being anticipated by Eriksson et al. (U.S. 2005/0059071 A1) is withdrawn.

EXAMINER'S AMENDMENT

9. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Angela Dallas Sebor on June 21, 2007.

Examiner's amendment to the claims:

1. (Currently Amended) An isolated peptide selected from the group consisting of:

a) a peptide consisting of SEQ ID NO:2;

b) ~~a peptide consisting of an amino acid sequence that is at least 70% identical to SEQ ID NO:2, wherein the peptide promotes myoblast differentiation;~~

e)——a peptide consisting of an amino acid sequence that differs from SEQ ID NO:2 by at least one substitution[[,]] ~~deletion or insertion~~ of an amino acid residue at a position of SEQ ID NO:2 selected from the group consisting of: 1, 2, 5, 6, 9, 10, 11, 12, 13, and 14, wherein the peptide promotes myoblast differentiation; and

[[d)]][c] a peptide consisting of an amino acid sequence that differs from SEQ ID NO:2 by substitutions at positions 1, 5, 6, 9, 11, and 14, wherein the peptide promotes myoblast differentiation;

wherein the amino acid residues substituted into positions 1, 2, 5, 6, 9, 10, 11, 12, 13, and 14 of SEQ ID NO:2 are those residues found at positions 1, 2, 5, 6, 9, 10, 11, 12, 13, and 14 in any of SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, and SEQ ID NO: 24, respectively.

Claim 23 (Currently Amended) A method to identify compounds that regulate myoblast activation and differentiation, comprising:

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a) contacting a prelamina A protein ~~represented by~~ (SEQ ID NO:4) or a prelamina A pre peptide ~~represented by~~ (SEQ ID NO:2) with a test compound under conditions suitable for binding of the prelamina A protein or prelamina A pre peptide by the test compound; ~~and~~

b) detecting binding of the prelamina A protein or prelamina A pre peptide by the test compound;

c) contacting myoblast with test compound of step b) that bind SEQ ID NO:2 or SEQ ID NO:4; and

d) detecting myoblast differentiation in the presence and absence of said test compound, thereby identifying said test compound that regulates myoblast differentiation.

Claim 47 (Currently Amended) The isolated peptide of Claim 1, wherein the peptide consists of an amino acid sequence that differs from SEQ ID NO:2 by at least one substitution of an amino acid residue at a position of SEQ ID NO:2 selected from the group consisting of: 1, 2, 5, 6, 9, 10, 11, 12, 13, and 14, wherein the peptide promotes myoblast differentiation.

Claim 48 (Currently Amended) The isolated peptide of Claim 1, wherein the peptide consists of an amino acid sequence that differs from SEQ ID NO:2 by at least one substitution of an amino acid residue at a position of SEQ ID NO:2 selected from the group consisting of: 1, 2, 5, 6, 9, 10, and 11, wherein the peptide promotes myoblast differentiation.

In claims 8, 14, 50-52, and 60 remove the word ---therapeutic---.

Cancel claims 2, 3, 5, 23, 42-46, and 58.

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Conclusion

10. Claims 1, 4, 6, 7, 8, 14, 23, 47, 48, 50-52, and 60-62 are allowed.
11. The following is an examiner's statement of reasons for allowance: The prior art does not disclose prelam A pre peptide (SEQ ID NO: 2) and prelam A (SEQ ID NO: 4) that promote the differentiation of myoblasts.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

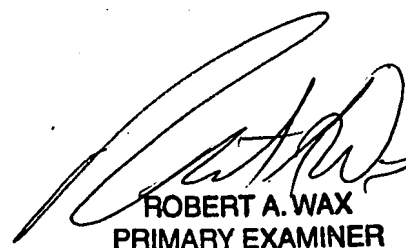
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 21, 2007

AD
/Anand Desai/
Patent Examiner
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ROBERT A. WAX
PRIMARY EXAMINER